REMARKS

This amendment responds to the first Office Action mailed August 18, 1999. By the accompanying Request for Extension of Time, a three-month extension of time in which to file this response is sought.

A CPA has been established. A terminal disclaimer has been received in the U.S. Patent and Trademark Office, and has been reviewed, accepted and recorded.

The specification has been corrected as helpfully suggested by the Examiner.

Claims 3, 4 and 6 have been amended in the manner helpfully suggested by the Examiner so as to overcome the Section 112 rejections.

The Examiner has remarked upon the proposition that this application names joint inventors. The subject matter of the various claims has been commonly owned throughout the development of this invention and throughout the prosecution of this application and its parent application.

Claims 2 and 6 have been rejected under Section 103 as obvious over Keller '432 in view of Buettner-Janz et al. '766. The Examiner believes it would have been obvious to have made the plates of Keller with convex outer surfaces, as taught by Buettner-Janz et al "since Applicant has not disclosed that these particular characteristics unexpectedly solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well as disclosed by Keller." Applicant respectfully traverses

this rejection. As originally presented in this application, claim 6 notes that each of the concaval-convex elements has "an outer surface of predetermined convexity and unreticulated surface roughness for engaging the adjacent bone structure which has been milled to mate with said outer convex surface and for encouraging bone ingrowth into the mating outer convex surface...". None of the cited patents teach "an outer surface of predetermined convexity and unreticulated surface roughness." None teach the use of such an unreticulated but rough surface for engaging adjacent bone structure "which has been milled to mate with said outer convex surface and for encouraging bone ingrowth into the mating outer convex surface...".

No cited patent teaches an unreticulated surface adapted to encourage bone ingrowth. There is no suggestion of milling a bone to a particular shape. There is no suggestion of providing the implant convex surfaces with a mating shape. None of the cited patents, alone or in combination, suggest engaging an adjacent bone structure which has been milled to a predetermined shape so as to mate with the predetermined outer convex surface shape of the implant.

And neither Keller '432 nor Buettner-Janz et al. '766, the reference applied against these claims, suggest encouraging bone ingrowth into the mating convex surface. Rather, both Keller "432 and Buettner-Janz et al. '766 provide "teeth 3" ('766) or similar "projections six" ('432) to affix the endoprosthesis within the adjacent bone structure. These teeth stress the

adjacent bone structure--something which is avoided by Applicant's claimed structure. This stress may weaken and fracture the impaled bone.

None of the references cited teach the concept of a rough, porous surface of predetermined convexity being mated closely with an adjacent bone structure which has been milled to provide the desired shape. Although Frey et al. '969 provides reticulated wire mesh "to connect the prosthesis with the vertebral bodies 1,2, by an ingrowth of bone tissue," (column 2, lines 43-45), there is no suggestion in any of the cited art of Applicant's roughened, unreticulated surface in any of these references.

But the implant defined in Applicant's novel claim 6 further patentability defines over the prior art. "Each concaval-convex element (also has) a smooth non-porous inner concave surface disposed to confront the opposed concaval-convex element smooth convex surface." Moreover, the implant also comprises "a solid but relatively resilient nuclear body located between the confronting concave surfaces...the nuclear body engaging but being separate from the adjacent concave surfaces to permit sliding arctuate movement of the concaval surfaces over the resilient nuclear body." This novel combination is not suggested by any combination of the cited art. Buettner-Janz et al. '766 implies clearly that the "spacing piece 4" is made of a rigid metal; "the spacing piece...is also provided with a high polish in order to minimize abrasion." (Column 5, lines 13-16). Keller '432 denominates a very similar "sliding body 4" which "normally consists of synthetic material."

(Column 5, line 2). There is no suggestion that the synthetic material is resilient; it is likely metal or some other rigid material. Frey et al. '969 (not applied in this rejection) provides a body 6 "which is filled with an incompressible fluid medium 8." (Column 2, lines 59-60). Although the body 6 may be deformable, it is not resilient. It is certainly not "solid" as claimed by Applicant. And Bainville et al. '294 provides an element 11 which consists of layers of material having different compressibility coefficients (see column 3, lines 33-38) but it is quite clear that this cushion element 11 does not slide with respect to the so-called cups 9 and 10. The circular ribs 12 would quite clearly prevent any sliding motion.

In summary, then, there is no suggestion anywhere in the art to provide a "relatively resilient convex nuclear body...between confronting concave surfaces...the nuclear body engaging but being separate from the adjacent concave surfaces to permit sliding arctuate movement of the concaval surfaces over the resilient nuclear body." This structure permits the inventor to provide a resilient vertebral disc endoprosthesis which will accommodate shocks and other forces applied to the spine. The device permits natural motion of the prosthetic parts and the adjacent natural anatomy and it will perform effectively and efficiently within a patient's spine over a long period of time. Importantly, it will not encourage degeneration of, or cause damage to, adjacent natural disc parts. All of these unexpected advantages are described at page 3 of the specification.

New claim 7 calls for the novel resilient convex nuclear body to be shaped and sized, relative to the concave surfaces of the concaval-convex elements, so as to be inhibited from expulsion from the endoprosthesis. None of the cited references suggest that appropriate shaping of the concave surfaces and the intermediate convex nuclear body will retain the nuclear body in its desired position between the convex surfaces. Only Frey '969 and Bainville et al. '294 offer anything remotely resembling a resilient nuclear body. Frey '969 is provided with "reinforcing means 11 to prevent excessive expansion of the body 6 in a radial direction" (column 3, lines 10-15), and Bainville et al. '294 provide a somewhat similar set of rings 15, 16, but no cited art suggest that claimed arrangement or suggest its advantages..

Accordingly, it is respectfully submitted that claims 6 and 7 each clearly define novel and patentable subject matter. Claims 2-5 depend on claim 6 and likewise are patentable.

Since the application appears in condition for allowance, an early action to that effect is earnestly solicited.

Respectfully submitted,

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